OST Medical

March 9, 2005

FDA, DISTRICT OFFICE
ONE MONTVALE AVE. 4th Flr
STONEHAM, MA 02180

Attention: Karen Archdeacon

RE: Response to 7-19-04 Warning Letter, NWE-31-04W

Dear Ms. Archdeacon,

OST Medical has received a letter from the Food and Drug Administration dated September 8, 2004. With respect to the subject of premarket notification (510(k) no. K011587), this letter states that, following a review of additional information provided by OST Medical, Inc., the FDA Center for Devices and Radiological Health (CDRH) has concluded that the documentation is adequate, and therefore, no new 510(k) is required at this time.

Sincerely,

Peter Sacchetti
President

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